MAR 1 3 2006 PAR 1

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313-1450, on the date shown below.

Dated: March 8, 2006

Signature: (Andrea Siverman)

Docket No.: AREX-P03-004

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Madiyalakan et al.

Application No.: 09/376,604

Confirmation No.: 6693

Filed: August 18, 1999

Art Unit: 1642

For:

THERAPEUTIC COMPOSITIONS THAT

ALTER THE IMMUNE RESPONSE

Examiner: G. B. Nickol

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Supplemental Information Disclosure Statement is filed more than three months after the U.S. filing date, and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

Applicant submits herewith copies of the cited foreign patent documents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

In accordance with 37 CFR 1.97(g), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Supplemental Information Disclosure statement shall not be construed to be an

Application No.: 09/376,604 Docket No.: AREX-P03-004

admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Supplemental Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Please charge our Deposit Account No. 18-1945 in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. AREX-P03-004. A duplicate copy of this paper is enclosed.

Dated: March 8, 2006

Respectfully submitted,

Gloria Fuentes

Registration No.: 47,580

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PTO/SB/17 (12-04v2)

Approved for use through 7/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).  FEE TRANSMITTAL For FY 2005  X Applicant claims small entity status. See 37 CFR 1.27  TOTAL AMOUNT OF PAYMENT  (\$) 180.00  Application Number  O9/376,604  Filing Date August 18, 1999  First Named Inventor Examiner Name G. B. Nickol  Art Unit 1642  AREX-P03-004					
First Named Inventor Ragupathy Madiyalakan Examiner Name G. B. Nickol  Art Unit 1642					
For FY 2005  First Named Inventor Ragupathy Madiyalakan Examiner Name G. B. Nickol  Art Unit 1642					
x Applicant claims small entity status. See 37 CFR 1.27 Art Unit 1642					
741.0111					
TOTAL AMOUNT OF PAYMENT (\$) 180.00 Attorney Docket No. AREX-P03-004					
METHOD OF PAYMENT (check all that apply)					
Check Credit Card Money Order Other (please identify):					
x Deposit Account Deposit Account Number: 18-1945 Deposit Account Name: Ropes & Gray LLP					
For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)					
x Charge fee(s) indicated below Charge fee(s) indicated below, except for the fill	ng fee				
x Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17					
FEE CALCULATION					
1. BASIC FILING, SEARCH, AND EXAMINATION FEES					
FILING FEES SEARCH FEES EXAMINATION FEES  Small Entity Small Entity  Application Type Fee (\$) Fee (\$) Fee (\$) Fee (\$) Fee (\$)  Fee (\$) Fee (\$) Fee (\$) Fee (\$) Fee (\$)	<u>\$)</u>				
Utility 300 150 500 250 200 100					
Design 200 100 100 50 130 65					
Plant 200 100 300 150 160 80					
Reissue 300 150 500 250 600 300					
Provisional 200 100 0 0 0					
	Entity				
Fee Description Each claim over 20 (including Reissues)  Fee (\$) Fee (	e (\$) 25				
Each independent claim over 3 (including Reissues) 200	100				
Multiple dependent claims 360	180				
Total Claims					
<sup>-233</sup> x = <u>Fee (\$)</u>					
Indep. Claims Extra Claims Fee (\$) Fee Paid (\$)					
3. APPLICATION SIZE FEE  If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).					
Total Sheets Extra Sheets Number of each additional 50 or fraction thereof Fee (\$) Fee Paid (\$)					
4. OTHER FEE(S)  Fees Paid (\$)					
Non-English Specification, \$130 fee (no small entity discount)  Other (e.g., late filing surcharge): 1806 Submission of an Information Disclosure Statement 180.00					
SUBMITTED BY					
Signature Registration No. (Attorney/Agent) 47,580 Telephone (617) 951-70	00				
Name (Print/Type) Gloria Fuentes Date March 8, 200	6				

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PTO/SB/08a/b (07-05)

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A TRADENT

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known			
Application Number	09/376,604		
Filing Date August 18, 1999			
First Named Inventor	Ragupathy Madiyalakan		
Art Unit	1642		
Examiner Name	G. B. Nickol		
Attorney Docket Number	AREX-P03-004		

	U.S. PATENT DOCUMENTS					
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where	
Initials*	No.1	Number-Kind Code <sup>2</sup> ( if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear	
	AA	US-5,240,833	08-31-93	Nudelman		
	AC	US-5,807,978	09-15-98	Kokolus		
	AD	US-6,088,613	07-11-00	Unger		

	FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	ВА	EP 0 153 871 A2	09-04-1985	Chang		
	BB	EP 0 315 456 B1	05-10-1987	Fagnani		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS		
Examiner Initials	• I magazine journal serial symposium catalog etc.) date nage(s) volume-issue number(s) nu			
	CA	ALGARRA et al., 1997, Altered MHC class I antigens in tumors, Int. J. of Clin & Lab. Res. 27:95-102 (Abstract only)		
	СВ	ANTONIA et al., 1995, Mechanisms of immune tolerance induction through the thymic expression of a peripheral tissue-specific protein, Int. Immunol. 7(5):715-725		
	CC	BAUM, 1994, Activating Anti-Idiotypic Human Anti-Mouse Antibodies for Immunotherapy of Ovarian Carcinoma, Cancer 73:1121-1125		
	CD	BENICHOU et al., 1994, Disruption of the determinant hierarchy on a self-MHC peptide: concomitant tolerance induction to the dominant determinant and priming to the cryptic self-determinant, Int. Immunol. 6(1):131-138		
	CE	BODEY et al., 2000, Failure of Cancer Vaccines: The Significant Limitations of this Approach to Immunotherapy, Anticancer Res. 20:2665-2676		
	CF	CIBOTTI et al., 1992, Tolerance to a self-protein involves its immunodominant but does not involve its subdominant determinants, Proc. Natl. Acad. Sci. USA 89:416-420		
	CG	GOLUMBEK et al., 1993, The Antitumor Immune-Response as a Problem of Self-Non-Self Discrimination – Implications for Immunotherapy, Immunologic Res. 12:183-192 (Abstract only)		
	СН	JACOBS and HASKELL, 1991, Clinical Use of Tumor Markers in Oncology, Curr. Probl Cancer 15(6):299-360		
	CI	LANZAVECCHIA, 1996, Mechanisms of antigen uptake for presentation, Curr. Opin. Imm. 8:348-354		
	CJ	LEE et al., 1999, Increased Vaccine-Specific T Cell Frequency After Peptide-Based Vaccination Correlates with Increased Susceptibility to In Vitro Stimulation But Does Not Lead to Tumor Regression, J. Immunol. 163:6292-6300		

Examiner	Date
Signature	Considered

PTO/SB/08a/b (07-05)

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Sut	ostitute for form 1449A/B/P	то		Complete If Known		
				Application Number	09/376,604	
l IN	NFORMATIO	N DIS	SCLOSURE	Filing Date	August 18, 1999	
l s	STATEMENT BY APPLICANT			First Named Inventor	Ragupathy Madiyalakan	
_				Art Unit	1642	
	(Use as many st	heets as	necessary)	Examiner Name	G. B. Nickol	
Sheet	2	of	2	Attorney Docket Number	AREX-P03-004	

Ck	Cancer Chemother. Pharmacol. 46(Suppl):S52-S61
CL	ÖHLÉN et al., 2001, Expression of a Tolerizing Tumor Antigen in Peripheral Tissue Does Not Preclude Recovery of High-Affinity CB <sup>+ T</sup> Cells of CTL Immunotherapy of Tumors Expressing the Antigen, J. Immunol. 166:2863-2870
CM	PANI, 1994, Failure of presented, nondominant self epitope to induce tolerance – implications for autoimmune-diseases, Immunological Investigations 23:337-346 (Abstract only)
	SEMINO et al., 1993, Heterogeneity of the alpha-interferon-mediated overexpression of class-I and class-II major histocompatibility complex molecules in primary cultured cancer cells, J. Biol. Reg. & Homeo. Agents 7:99-105
CC	WATTS and LANZAVECCHIA, 1993, Suppressive Effect of Antibody on Processing of T Cell Epitopes, J. Exp. Med. 178:1459-1463

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date
Signature	Considered

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.